In the United States Court of Federal Claims office of special masters

No. 24-0080V

DOMINIQUE WILLIAMS, for and on behalf of his Minor Child, A.I.W.,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES.

Respondent.

Chief Special Master Corcoran

Filed: March 25, 2025

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM¹ AND ORDER TO SHOW CAUSE – SPECIAL PROCESSING UNIT

On January 19, 2024, Dominique Williams, for and on behalf of his minor child, A.I.W., filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleged that A.I.W. suffered from intussusception resulting from a rotavirus vaccine received on February 22, 2021. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

On January 3, 2025, Respondent filed a Rule 4(c) Report and Motion to Dismiss (ECF No. 22) ("Mot."). Respondent acknowledges that the facts of this case appear to meet the definition of intussusception as defined by the Vaccine Injury Table. Mot. at *9. But he nevertheless argues that Petitioner's injury does *not* meet the statutory severity requirement applicable to *all* claims. *Id.* at 5-9. This is because Petitioner cannot show

¹ Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Fact Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

the "surgical intervention" exception to the six-month severity timeframe is not met, given the treatment for intussusception received by A.I.W.

Petitioner was directed to respond to the motion to dismiss by March 3, 2025. Scheduling Order (NON PDF), issued Jan. 3, 2025. Petitioner did not file a response, however. Instead, on March 3, 2025, Petitioner's counsel filed a motion to withdraw (ECF No. 23). Petitioner's counsel stated that he had notified Petitioner in writing by regular mail, certified mail, and email of his intent to withdraw, and while a United States Postal Service letter to Petitioner's address was returned to counsel, Petitioner responded to the email and requested a copy of his case documents.

I. Relevant Evidence

On February 22, 2021, at the age of four months, A.I.W. received her second dose of rotavirus vaccine. Ex. 4 at 11, 12, 66. Ten days later, at 8:10 PM on the evening of March 4, 2021, A.I.W. was brought to the emergency department ("ED") due to vomiting that began that afternoon. Ex. 3 at 56. Emergency medicine Dr. Lindsay Day examined A.I.W. and determined that her symptoms were "concerning for obstruction," and ordered an ultrasound to check for intussusception. *Id.* at 59.

The ultrasound showed that A.I.W. had experienced an intestinal intussusception. Ex. 3 at 87. Surgical physician assistant ("PA") Stephanie McGee reviewed the ultrasound and determined that A.I.W. should be taken to the radiology department for an air enema to reduce the intussusception. *Id.* If the enema was successful, an intussusception algorithm would be followed, with a trial of oral feeding followed by observation. *Id.* Otherwise, or if A.I.W. was unable to tolerate feeding, PA McGee planned to "notify [the] surgery team for admission." *Id.*

The enema was administered at 10:50 PM on March 4th, the day A.I.W. arrived at the ED. Ex. 3 at 70, 94. It successfully reduced A.I.W.'s intussusception. *Id.* at 94. Because it was successful, the intussusception algorithm was followed. By 4:19 AM on March 5, 2021, A.I.W. was "tolerating breast feeding." *Id.* at 81. A.I.W. was observed until nearly 6:00 AM, then discharged home after spending approximately ten hours in the ED. *Id.* at 84.

Four days later (March 8, 2021), A.I.W. was seen by her pediatrician for a follow-up appointment. Ex. 4 at 52. The record notes that A.I.W. was "[a]dmitted to ER 4 days ago for intussusception. Resolve[d] with air enema. Doing much better." *Id.* at 53. Due to the temporal proximity of A.I.W.'s rotavirus vaccine and her intussusception, her pediatrician recommended not giving her the third dose of the rotavirus vaccine, and A.I.W.'s mother agreed. *Id.* at 54. The record does not indicate that A.I.W. was experiencing any residual effects from her intussusception, and Petitioner has not filed any subsequent medical records.

Petitioner submitted a declaration from Ashley Williams, A.I.W.'s mother. Ex. 6. Ms. Williams states that at dinner time on March 4, 2021, A.I.W. was fussy, would not nurse, looked like something was "off," and vomited. Ex. 6 at ¶ 4. Ms. Williams scheduled a virtual urgent care appointment, during which she was told to take A.I.W. to the ED. *Id.* at ¶ 4.

Ms. Williams states that the hospital "admitted [A.I.W.] as a patient and performed surgery to repair the issue." Ex. 6 at \P 6. A.I.W. was discharged the next day. *Id.* She adds that "[a]fter a few days, A.I.W.'s health had returned to normal and she no longer had the symptoms associated with intussusception." *Id.* at \P 8.

II. Severity Requirement in Intussusception Cases

Intussusception as defined in the Qualifications and Aids to Interpretations ("QAI") is a time-limited injury involving "invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus." 42. C.F.R. § 100.3(b)(4)(i).

Intussusception is an acute, life-threatening illness. But it is by definition a self-limiting condition, and most cases are successfully treated. *Carda v. Sec'y of Health & Human Servs.*, No. 14-191V, 2017 WL 6887368, at *19 (Fed. Cl. Spec. Mstr. Nov. 16, 2017). And while surgical intervention can be required to resolve it, intussusception can also be successfully treated with far less-invasive methods, such as an air enema. *Id.* at *19.

All Vaccine Act claims are subject to the Act's "severity" test, and in most instances it can be met if the claimant demonstrates six months of post-onset sequelae. Vaccine Act § 11(c)(1)(D). But an acute and inherently self-limiting injury like intussusception will usually be resolved successfully well within that timeframe. Because the Government deemed the association between intussusception and the rotavirus vaccine to be otherwise demonstrated, and out of a desire to make it a potentially actionable claim, the Vaccine Act was amended in 2000 to allow the severity requirement to be met by showing that the injured person underwent surgical intervention and inpatient hospitalization. Children's Health Act of 2000, Pub. L. No. 106-310, Sec. 1701 (2000).³

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At the time this law was enacted, parameters were established to permit claims for those serious adverse events that were known to be associated with those vaccines that were then available. The statutory proxy for a serious injury is that the residual effect from the injury must be of six months' duration or longer.

³ One of the Senate bill's sponsors explained the reason for the amendment:

In so doing, however, Congress did not act to make cases treated by more limited means compensable. And in fact, prior Program cases have consistently determined that an enema is not a surgical intervention. See Zhao v. Sec'y of Health & Human Servs., No. 19-735V, 2023 WL 2337287, at *8 (Fed. Cl. Spec. Mstr. Jan. 25, 2023) (stating that "[b]arium contrast enemas are non-surgical interventions" and dismissing case); Godoy v. Sec'y of Health & Human Servs., No. 20-1292V, 2022 WL 19026215, at *11 (Fed. Cl. Spec. Mstr. Dec. 2, 2022) (dismissing Table intussusception claim because barium enema was not surgical intervention); Green v. Sec'y of Health & Human Servs., No. 19-1295V, 2020 WL 1845325, at *1 (Fed. Cl. Spec. Mstr. Mar. 18, 2020) (dismissing intussusception claim at the petitioner's request and noting that "the Court has repeatedly held that intussusception treated with a barium enema does not qualify as surgical intervention" and thus the severity requirement was not met); Parsley v. Sec'y of Health & Human Servs., No. 08-781V, 2021 WL 2463539, at *n.19 (Fed. Cl. Spec. Mstr. May 27, 2011) (noting that "[t]he parties have agreed that the barium enema was not a 'surgical procedure" under the Vaccine Act).

In this case, there does not appear to be any dispute that A.I.W. did *not* suffer from residual effects or complications of her injury for more than six months. Her condition was successfully treated less than a day after it began. And by March 8, 2021 – four days after the onset of her condition - A.I.W. was "much better" and no longer suffering intussusception symptoms. Ex. 4 at 53; Ex. 6 at ¶ 8. Nor did she undergo a surgical intervention for treatment of the intussusception.

Recently, however, a new situation has developed that was not foreseeable at the time of enactment of this law. In October 1999, the CDC's Advisory Committee on Immunization Practices (ACIP), after a review of scientific data from several sources, concluded that intussusception occurs with significantly increased frequency in the first 1-2 weeks after vaccination for rotavirus, particularly after the first dose.

While most cases of intussusception require only minimal treatment, a few cases require hospitalization and surgery. Under the current law, these cases would not be compensable by the United States Claims Court under the Vaccine Injury Compensation Program, since the statute grants jurisdiction to resolve vaccine cases only in instances in which claimants have suffered the residual effects or complications of a vaccinerelated injury for at least six months, or died from the administration of a vaccine.

For this reason, we are offering this bill to amend the law and grant jurisdiction to the Claims Court to resolve compensation cases under the Program in cases in which both hospitalization and surgical intervention were required to correct the "illness, disability, injury or condition" caused by the vaccine.

145 Cong. Rec. S15213-14 (Nov. 19, 1999) (Statement of Sen. Jeffords).

It also does not appear that A.I.W. underwent an inpatient hospitalization, given that she was treated in the ED and never formally admitted to the hospital. In *Uetz v. Sec'y of Health & Human Servs.*, No. 14-29V, 2014 WL 7139803, at *4 (Fed. Cl. Spec. Mstr. Nov. 21, 2014), the special master determined that the petitioner did not establish an inpatient hospitalization when she was treated and released from an ED on the same day. A.I.W. was treated only in the ED, where she stayed for approximately ten hours. And after the enema was successful, and A.I.W. was able to tolerate feeding several hours later, she was discharged from the ED.

Given the above, Petitioner cannot succeed on a Table claim in this matter, and that claim is properly dismissed. I will provide Petitioner the opportunity to sketch out what a non-Table claim in this case (which would also need to meet the severity requirement) pursuant to the *Althen* factors⁴ might look like – but if this cannot be done by reference to additional evidence not yet offered in this case, the entire claim is subject to dismissal.

Conclusion

Petitioner's claim cannot proceed without sufficient evidence, and will be dismissed absent additional evidence. Failure to file the medical records and other evidence sufficient to support a claim will result in dismissal of the claim. *Tsekouras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 439 (1992), aff'd, 991 F.2d 810 (Fed. Cir. 1993) (per curiam); *Sapharas v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

In the event that Petitioner decides not to pursue the petition further, Petitioner is advised to consult with Section IX of the Guidelines for guidance on the appropriate notice, motion, or stipulation to file to exit the vaccine program. The Guidelines may be found here:

https://www.uscfc.uscourts.gov/sites/cfc/files/Vaccine%20Guidelines%203.03.2025.pdf

Accordingly:

Petitioner's counsel shall file, by no later than <u>Tuesday</u>, <u>April 08</u>, <u>2025</u>, a status report (1) confirming that he has provided a copy of this Order to Petitioner, and (2) providing an updated mailing address for Petitioner.

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⁴ Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) (setting out a three part test for causation in fact claims, requiring that a petitioner establish (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury).

- Petitioner shall file, by no later than Wednesday, May 28, 2025, either:
 - The appropriate motion, notice, or stipulation needed to dismiss the claim; or
 - A response to this Order, preferably including additional evidence, showing cause why this case should not be dismissed for failure to establish entitlement to compensation.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran Chief Special Master